A Phase II Study of Autologous CD4-zeta Gene-Modified T Cells in HIV Infected Patients with Undetectable Plasma Viremia on Highly Active Anti-Retroviral Drug Therapy.

Non-technical abstract:

HIV infection progressively destroys the human immune system and results in AIDS in the majority of patients. There is currently no cure for HIV infection or AIDS. White blood cells called CD8+ T cells kill cells infected with viruses and are an important component of the body's defense against viral infections. Although CD8+ T cells play an important role in temporarily controlling HIV infection, data suggest that a breakdown of the cell response may be responsible to progression to AIDS. CD4+ helper T cells are believed to be necessary for the persistence of CD8+ T cells; AIDS patients experience a loss of HIV-specific CD4+ T cells early in HIV infection. Cell Genesys, Inc. has designed a receptor, CD4-zeta, that when expressed on CD8+ and CD4+ T cells will help those cells recognize HIV-infected cells and kill them.

In the proposed clinical study, CD8+ and CD4+ T cells will be removed from HIV-infected patients with CD> 200 and viral load < 40 copies/mL. Half of the patients enrolled in this study will have their T cells modified by genetically inserting the gene for the CD4-zeta receptor. The gene-modified cells will be expanded to large numbers in the laboratory before infusion into the patient. The other half will receive their own cells back after they have been expanded in the laboratory, but they will not be genetically modified. The study will evaluate the antiviral activity, persistence, and safety of the T cells that are infused into every patient. By monitoring immune status, viral burden, organ function, and persistence of the cells in the body, we hope to determine whether this potential therapeutic approach is active and safe.